OCT - 3 2000

XI. 510(K) SUMMARY

A. Sponsor/Submitter: Perclose, Inc.
400 Saginaw Drive
Redwood City, CA 94063
Tel: (650) 474-3000
Fax: (650) 474-3100

B. Contact Person: Denise C. Singleton, JD, RAC
Senior Regulatory Affairs Coordinator
(650) 474-3193

C. Date of Submission: June 2, 2000

D. Trade (Brand) Name: Perclose Vascular Suture Delivery Device

E. Common Name: Suture Delivery Device

F. Classification: Class II

G. Classification Name: To Be Determined

H. Product Code: To Be Determined

I. Predicate Devices:

1. U.S. Surgical Corporation (Vascular Therapies) Auto Suture SurgiStitch, K972911
2. Sutura, Inc. SuperStitch, K994087

J. Intended Use:

The Perclose Vascular Suture Delivery Device is intended for use in the delivery of 10 interrupted sutures to assist the surgeon in the creation of vascular anastomoses.

K. Device Description:

The Perclose Vascular Suture Delivery Device is a hand-held surgical device that simultaneously deploys 10 lengths of 7-0 polypropylene suture at the site of a vascular anastomosis via a hydraulic delivery mechanism. The Perclose Vascular Suture Delivery Device is available in two models for creating either side-to-side or end-to-side anastomoses. After deployment of the device, the surgeon completes the anastomosis by hand-tying the appropriate surgical knots. Optional accessories available for use with the Perclose Vascular

Suture Delivery (PVSD) Device include the PVSD Scissors, RC2000 Flexible Device Holder, Suture Combs, and PVSD Handle.

The Perclose Vascular Suture Delivery Device is a prescription device, restricted to use by physicians trained in vascular surgery.

The Perclose Vascular Suture Delivery Device is EtO sterilized and non-pyrogenic in an unopened undamaged package, for single use only.

F. Summary of Substantial Equivalence:

Perclose, Inc. has submitted information on design, indications, materials, and principle of operation to establish that the Perclose Vascular Suture Delivery Device is substantially equivalent to currently marketed predicate devices.

The Perclose Vascular Suture Delivery Device has essentially the same intended use as the predicate devices. Questions regarding the effects of any new technological characteristics of the Perclose Vascular Suture Delivery Device have been answered through accepted scientific methods. These methods assessed the new characteristics with regard to functionality and reliability under simulated and actual conditions of use. Results of scientific testing have ensured that different materials are biocompatible and physical properties are appropriate for the intended use. Scientific tests conducted to ensure the safety and effectiveness of the Perclose Vascular Suture Delivery Device included:

- Dermal Sensitization
- Cytotoxicity
- Intracutaneous Reactivity
- Systemic Toxicity
- Hemolysis
- Thrombogenicity
- Attachment strength of critical components
- Functional bench testing (e.g., suture deployment, suture spacing, suture management, tissue capture)
- *In vivo* animal testing

In conclusion, the Perclose Vascular Suture Delivery Device has been shown to be substantially equivalent to the Class II predicates on which the device is based.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT - 3 2000

Ms. Denise C. Singleton, JD, RAC
Senior Regulatory Affairs Coordinator
Perclose, Inc.
400 Saginaw Drive
Redwood City, California 94063

Re: K001703
Trade Name: Perclose Vascular Suture Delivery Device
Regulatory Class: II
Product Code: GAW, HCF, GAB
Dated: July 28, 2000
Received: August 1, 2000

Dear Ms. Singleton:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4595. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

X. INDICATIONS FOR USE STATEMENT

510(k) Number: To Be Determined K001703

Device Name: Perclose Vascular Suture Delivery Device

Indications for Use: The Perclose Vascular Suture Delivery Device is indicated for use in the delivery of 10 interrupted sutures to assist the surgeon in the creation of vascular anastomoses.

Mark N. Melkerson

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K001703